

Certificate of Analysis

Product name: **Sulfadiazinum argenticum micr.**

Batch number / Weight: **21K27-B03-216464 / 10 G**

Analysed according to: **USP**

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------------------|--|---------|------|-----------------|
| Appearance | White to creamy-white, crystalline powder | Conform | | |
| Particle size | 100%<50µm / >= 99%<25µm / >=95%<10µm | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | Conform | Conform | | |
| Identification C | Conform | Conform | | |
| Loss on drying | <=0,5 | 0,08 | % | |
| Nitrates | <=0,1 | Conform | % | |
| Related substances | Conform | Conform | % | |
| Sulfanilic acid | <=0,3 | <0,05 | % | |
| Sulfaguanidine | <=0,10 | <0,05 | % | |
| Sulfanilamide | <=0,10 | <0,05 | % | |
| 2-aminopyrimidine | <=0,3 | <0,05 | % | |
| Acetylsulfadiazine | <=0,2 | <0,05 | % | |
| Specified unidentified impurity | <=0,15 | <0,05 | % | |
| Individual unspecified impurity | <=0,10 | <0,05 | % | |
| Total impurities | <=0,5 | <0,05 | % | |
| Silver | 29,3 - 30,5 | 29,8 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | |
| Assay Silver sulfadiazine | 98,0 - 102,0 | 98,9 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | |

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

27-05-2022

Expiration: 02-11-2026

Conclusion: APPROVED

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